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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
08/837,301	04/11/97	STEVEN A	14014.0327

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ART UNIT	**PAPER NUMBER**
1641	14

DATE MAILED: 09/25/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.	Applicant(s)
08/837,301	Alasdair C. Steven
Examiner	**Group Art Unit**
Lisa V. Cook	1641

☒ Responsive to communication(s) filed on *Sep 5, 2000*

☐ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *3* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claim

☒ Claim(s) *57-97* is/are pending in the applicat

Of the above, claim(s) *68-97* is/are withdrawn from consideration

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) *57-67* is/are rejected.

☐ Claim(s) _____ is/are objected to.

☒ Claims *57-97* are subject to restriction or election requirement.

Application Papers

☒ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☒ The specification is objected to by the Examiner.

☒ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☒ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____ .

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). *7*

☐ Interview Summary, PTO-413

☒ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

* Sequence letter

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

DETAILED ACTION

Election/Restrictions

1. Applicants' provisional election of Group I –claims 57-67, with traverse is acknowledged. (Paper # 13, filed 05 September 2000). Applicant does not traverse the Restriction Requirement because it lacks patentable distinctness. But objects on the ground(s) "that the examiner has not shown that a serious burden would be required to examine all of the claims". This argument has been fully considered, but is not found convincing.

2. This is not found persuasive because MPEP § 808.02 recites:

> Where related inventions as claimed are shown to be distinct under the criteria of MPEP § 806.05(c)- § 806.05(i), the examiner, in order to establish reasons for insisting upon restriction, must show by appropriate explanation one of the following: (A) Separate classification thereof, (B) A separate status in the art when they are classified together, or (C) A different field of search.

3. In the instant case, (A) -The Restriction Requirement under 35 U.S.C. § 121 in Paper #12 established distinctness of the inventions and separate classification thereof:

4. (B) The inventions of Groups I, II, III, and IV would require a separate status in the art when they are classified together; the invention as a whole is drawn to a composition having utility in mammalian immunization/disease protection. Such inventions are classified in 514, subclass 2 for example.

5. (C) With respect to a different field of search – Because these inventions are distinct and have acquired separate status in the art as shown by their different classification, recognized divergent subject matter and because the search required for each invention is not substantially coextensive with the search required for the remaining invention, restriction for examination purposes as indicated is proper. Please note that the classifications in the restriction are illustrative only and do **not** represent all the classes and subclasses which must be searched for each invention; nor is the search limited to issued US patents, but rather includes published foreign patents and applications as well as literature search.

6. Further, the combination of Groups I, II, III and IV (claims 57-97) for examination on the merits is deemed incorrect. The merging of these groups would combine patentably distinct inventions. Claims 57-97 link(s) invention II, III, and IV. The restriction requirement (as set forth in paper #12) separating the linked inventions is subject to the nonallowance of the linking claim(s), 57-96 (Product). Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application.

Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be

subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. See *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01. *See in re Ochiai*, 71 F.3d 1565, 37 USPQ2d 1127 (Fed. Cir. 1995) 706.02(n), 2116.01. For these reasons the inventions of Groups I, II, III and IV were not joined.

The Restriction Requirement is still deemed proper and is therefore made **FINAL.**

7. Currently, claims 57-97 are subject to Restriction and Election Requirement. Claims 68-97 have been withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as claims drawn to a non-elected invention. Claims 57-67 are currently pending and under examination.

Priority

8. The instant application does not claim priority or benefits to an earlier application.

Drawings

9. The drawings in this application are objected to by the Draftsperson under 37 CFR 1.84 or 1.152 (see PTO-948). Applicant is required to submit a proposed drawing correction in reply to this Office action. However, formal correction of the noted defect can be deferred until the application is allowed by the examiner.

Information Disclosure Statement

10. The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609 A(1) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the Examiner on form PTO-892 or Applicant on form PTO-1449 has cited the references they have not been considered.

Oath/Declaration

11. A new oath or declaration is required because:

A. Non-initialed and/or non-dated alterations have been made to the oath or declaration. See 37 CFR 1.52(c). Please see the entries for citizenship for each inventor.
B. Applicant has not given a post office address anywhere in the application papers as required by 37 CFR 1.33(a), which was in effect at the time of filing of the oath or declaration. A statement over applicant's signature providing a complete post office address is required.
C. The specification to which the oath or declaration is directed has not been adequately identified. See MPEP § 601.01(a). Please check the appropriate line.

The wording of an oath or declaration cannot be amended. If the wording is not correct or if all of the required affirmations have not been made or if it has not been properly subscribed to, a new oath or declaration is required. The new oath or declaration must properly identify the application of which it is to form a part, preferably by application number and filing date in the body of the oath or declaration. See MPEP §§ 602.01 and 602.02.

Specification

12. The specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification. The disclosure is objected to because of the following informalities: The first page of the specification is not numbered. Appropriate correction is required.

Sequence Non-compliance

13. This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the reason(s) set forth on the attached Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures. Applicant must comply with the requirements of the sequence rules (37 CFR 1.821 - 1.825) before the application can be examined under 35 U.S.C. §§ 131 and 132.

Applicant is given THREE MONTHS from the mailing date of this communication within which to comply with the sequence rules, 37 CFR 1.821 - 1.825. Failure to comply with these requirements will result in ABANDONMENT of the application under 37 CFR 1.821(g). Extensions of time may be obtained by filing a petition accompanied by the extension fee under the provisions of 37 CFR 1.136(a). Direct the reply to the undersigned. Applicant is requested to return a copy of the attached Notice to Comply with the reply.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

14. Claims 57-67 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A. Claim 57 is vague and indefinite because it is unclear as to what the term "comprising" entails. The claim recites a composition containing a T4 surface lattice protein and a chimera comprising. Is this wording referring to only the chimera composition or is it referring to the composition of both the T4 surface lattice protein and the chimera? Please explain.

B. Claim 63 ambiguous in utilizing the phrase "encodes a dispensable polypeptide". The recited claim is unclear because it is not known if the composition contains more than one dispensable polypeptide? (i.e. the dispensable polypeptide derived from a member of the T4 virus family that encodes a [second] dispensable polypeptide). Please clarify.

Claim Rejections - 35 USC § 102

15. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

I. Claims 57-67 are rejected under 35 U.S.C. 102(a) as being anticipated by Ren et al. (Protein Science (1996), Vol.5, pages 1833-1843).

Ren et al. teach compositions in which molecules of interest are displayed through polymer binding. The polymers are T4 capsids and polyheads (tubular capsid variants) and the display molecules are derivatives of the dispensable capsid protein SOC. (Abstract). In figure 1, on page 1834 – the principle of the SOC display system is outlined. A surface lattice of the T4 capsid contains two dispensable proteins, SOC and HOC (claims 64 and 65). The surface lattice protein is a hexagonal array of hexamers of protein gp23*. HOC and SOC bind to the outer surface of the gp23* lattice: a HOC monomer binds at the center of each hexamer, and trimers of SOC bind around the trigonal sites. Peptides or polypeptides (examples with 4-residue and 316-residue peptides are shown) are expressed/displayed as C-terminal fusions of SOC and bind to the display platform. The mature surface lattice does not dissociate over a wide range of concentrations and environmental conditions. The composition is taught to be suitable in expressing an antigen (see page 1838), an enzyme see page 1839-(induce

T-cell response), and an immunoglobulin (see page 1836-Immunogenicity of SOC-V3 phage). Also see page 1839-Potential application of the SOC system.

II. Claims 57, 62, 63, 64, 66, and 67 are rejected under 35 U.S.C. 102(b) as being anticipated by Macdonal et al. (Embro Journal, 12/1984, Vol.3, No.12, pages 2863-2871)-ABSTRACT ONLY.

Macdonald et al. disclose DNA sequence and transcriptional patterns in T4 phage (*T4 surface lattice protein array*). The T4 phage is taught to be a suitable lattice protein in the instant invention. See the specification, page2, lines 1-2 and page 12, lines 11-18. In an area between 15 and 18 kb on the standard phage T4 map, the novel gene 69 is localized. This 69 gene (*molecule of interest*) codes for two overlapping proteins that share a common C-terminal segment. The two proteins are expressed from different transcripts that are under different regulation. The smaller protein, gp69*, can be expressed from a Escherichia coli-like promoter, but the expression of the larger protein, gp69 is delayed. The gene (69) is bracketed by DNA adenine methylase (*linker*) and the late gene SOC (*T4 dispensable polypeptide*).

Claim Rejections - 35 USC § 103

16. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

Claims 58, 59, 60, 61, and 65 are rejected under 35 U.S.C. 103(a) as being unpatentable over Macdonal et al. (Embro Journal, 12/1984, Vol.3, No.12, pages 2863-2871)-ABSTRACT ONLY in view of U. Aebi et al. (J. Mol. Biol., 1977, 110, pages 687-698) and Ladner et al. (USP#5,403,484).

Please see discussion of Macdonald et al. as set forth above.

Macdonald et al. differ from the instant invention in failing to teach the dispensable polypeptide-HOC and the different types of molecules of interest that may be expressed in this system (antigen, enzyme, or immunoglobulin).

However, U.Aebi et al. disclose that the T4 phage has two dispensable capsids namely, soc and hoc. (page 687)

Ladner et al. (USP#5,403,484) show that viruses expressing chimeric binding proteins can be useful in producing novel enzymes and hormones. (column 16, lines 1-8).

Macdonald et al., U. Aebi et al., and Ladner et al., are all analogous art because they are from the same field of endeavor, all three inventions teach expression techniques involving phage display.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use the HOC as a dispensable polypeptide and express antigens, enzymes, or immunoglobulins as specific molecules of interest as taught by U. Aebi et al. and Ladner et al. in the method of Macdonald et al. to perform outer capsid phage display, because such dispensable polypeptides and molecules of interest as taught by U. Aebi et al. and Ladner et al. are well known in the art. A person of ordinary skill in the art would have had a reasonable expectation of success utilizing such materials, because they were already shown to be operable in the prior art.

One having ordinary skill in the art would have been motivated to do this because Ladner et al. taught that the expressed protein binding characteristic could be determined by controlled genetic variations, which are able to select mutated genes with specific novel proteins having desirable binding properties (much more predictable). See Column 7 and Column 8.

17. For reasons aforementioned, no claims are allowed.

Remarks

18. Prior art made of record and not relied upon is considered pertinent to the applicant's disclosure:

A. Huang et al. (Gene, 151, (1994) pages 143-145) teach a process for utilizing a small, high copy number vector to express a gene *in vitro* or *in vivo*.

19. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform to the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The Group 1641 Fax number is (703) 308-4242, which is able to receive transmissions 24 hours/day, 7 days/week.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lisa V. Cook whose telephone number is (703) 305-0808. The examiner can normally be reached on Monday-Friday from 8:00 AM - 4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le, can be reached on (703) 305-3399.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Lisa V. Cook
CM1-7D16
(703) 305-0808
07/12/00

LONG V. LE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

Application No.: 08/837,301

NOTICE TO COMPLY WITH REQUIREMENTS FOR PATENT APPLICATIONS CONTAINING NUCLEOTIDE SEQUENCE AND/OR AMINO ACID SEQUENCE DISCLOSURES

Applicant must file the items indicated below within the time period set the Office action to which the Notice is attached to avoid abandonment under 35 U.S.C. § 133 (extensions of time may be obtained under the provisions of 37 CFR 1.136(a)).

The nucleotide and/or amino acid sequence disclosure contained in this application does not comply with the requirements for such a disclosure as set forth in 37 C.F.R. 1.821 - 1.825 for the following reason(s):

- [X] 1. This application clearly fails to comply with the requirements of 37 C.F.R. 1.821-1.825. Applicant's attention is directed to the final rulemaking notice published at 55 FR 18230 (May 1, 1990), and 1114 OG 29 (May 15, 1990). If the effective filing date is on or after July 1, 1998, see the final rulemaking notice published at 63 FR 29620 (June 1, 1998) and 1211 OG 82 (June 23, 1998).
- [X] 2. This application does not contain, as a separate part of the disclosure on paper copy, a "Sequence Listing" as required by 37 C.F.R. 1.821(c).
- [X] 3. A copy of the "Sequence Listing" in computer readable form has not been submitted as required by 37 C.F.R. 1.821(e).
- [ ] 4. A copy of the "Sequence Listing" in computer readable form has been submitted. However, the content of the computer readable form does not comply with the requirements of 37 C.F.R. 1.822 and/or 1.823, as indicated on the attached copy of the marked -up "Raw Sequence Listing."
- [ ] 5. The computer readable form that has been filed with this application has been found to be damaged and/or unreadable as indicated on the attached CRF Diskette Problem Report. A Substitute computer readable form must be submitted as required by 37 C.F.R. 1.825(d).
- [ ] 6. The paper copy of the "Sequence Listing" is not the same as the computer readable from of the "Sequence Listing" as required by 37 C.F.R. 1.821(e).
- [ ] 7. Other: _____

Applicant Must Provide:

- [X] An initial or substitute computer readable form (CRF) copy of the "Sequence Listing".
- [X] An initial or substitute paper copy of the "Sequence Listing", as well as an amendment directing its entry into the specification.
- [X] A statement that the content of the paper and computer readable copies are the same and, where applicable, include no new matter, as required by 37 C.F.R. 1.821(e) or 1.821(f) or 1.821(g) or 1.825(b) or 1.825(d).

For questions regarding compliance to these requirements, please contact:

For Rules Interpretation, call (703) 308-4216
For CRF Submission Help, call (703) 308-4212
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